

K121443

# 510K Summary

 We are **smith&nephew**

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|--|---|-------------|
| <b>Submitted by:</b>                             | Smith & Nephew, Inc.<br>Orthopaedic Division<br>1450 East Brooks Road<br>Memphis, Tennessee 38116         | AUG 13 2012 |
| <b>Date of Summary:</b>                          | July 25, 2012   |             |
| <b>Contact Person and Address:</b>               | Shereen Myers, Senior Regulatory Affairs Specialist<br>T (901) 399-6325 F (901) 566-7075                  |             |
| <b>Name of Device:</b>                           | Smith & Nephew, Inc Journey II CR Knee System   |             |
| <b>Common Name:</b>                              | Knee prosthesis   |             |
| <b>Device Classification Name and Reference:</b> | 21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis |             |
| <b>Device Class:</b>                             | Class II  |             |
| <b>Panel Code:</b>                               | Orthopaedics/87   |             |
| <b>Product Code:</b>                             | JWH   |             |

## Device Description

Subject of this Abbreviated Premarket Notification are the Journey II Knee system. This 510(k) was prepared in accordance with the Agency's, "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses," dated April 1993. The subject device is a cruciate retaining (CR) total knee system which provides the ability for greater flexion to those patients who have the anatomical capability to allow a greater flexion range.

Components of this premarket notification include the following components:

- Cruciate retaining femoral components which will initially be available in sizes 1-10 in right and left designs in OXINIUM material.
- Cruciate retaining femoral components which will initially be available in sizes 1-9 in right and left designs in cobalt chrome material
- Cruciate retaining articular inserts which will initially be available in sizes 1-2, 3-4, 5-6, and 7-8 in right and left designs. Journey II CR articular inserts will be offered in 9-21 mm thicknesses and manufactured from cross-linked polyethylene or UHMWPE.

The Journey II CR Knee system will use existing cemented Journey tibial tray and patellar components currently used with the Journey BCS Knee System (K042515), Journey II Deep Dished articular insert components (K113482), and existing patellar components of the Genesis II Knee System (K951987)

## Technological Characteristics

This 510(k) was prepared in accordance with the Agency's, "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses," dated April 1993. A review of the mechanical data indicates that the Journey II CR Knee System is capable of withstanding expected *in vivo* loading without failure. The following mechanical testing of the Journey II CR Knee system was performed:

- Patellofemoral Contact Area Analysis
- Tibiofemoral Contact Area Analysis

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- Patellofemoral Resistance to Lateral Subluxation
- Tibiofemoral Constraint Testing

A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices

#### Intended Use

Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

- The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

#### Substantial Equivalence Information

The substantial equivalence of the Journey II CR Knee system is based on its similarities in indications for use, design features, and operational principles to the predicate systems listed in the following table.

Table 1: Comparison to Substantially Equivalent Devices

| Design Aspect Reviewed        | Journey II CR Knee System                          | Journey II BCS Knee System                         | Journey CR Knee System                    |
|-------------------------------|--|--|---|
| 510(k) Number                 | Subject 510(k)                                     | K111711  | K101499                                   |
| Manufacturer                  | Smith & Nephew, Inc                                | Smith & Nephew, Inc                                | Smith & Nephew, Inc                       |
| Similar Indications for Use   | Subject device                                     | Y  | Y   |
| Insert Locking Mechanism      | Y  | Y  | Y   |
| Similar Sterilization Method  | Subject device                                     | Y  | Y   |
| Material                      | Femoral – OXNIUM and CoCr Insert - XLPE and UHMWPE | Femoral – OXNIUM and CoCr Insert - XLPE and UHMWPE | Femoral – OXNIUM and CoCr Insert - UHMWPE |
| Similar Manufacturing Process | Subject device                                     | Y  | Y   |

#### Conclusion

As previously noted, this Abbreviated 510(k) Premarket Notification is being submitted to request clearance for the Journey II CR Knee System. Based on the similarities to the predicate components and a review of the validation testing performed, the device is substantially equivalent to above predicate systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room --WO66-G609  
Silver Spring, MD 20993-0002

AUG 13 2012

Smith & Nephew, Inc.  
% Ms. Shereen Myers  
Senior Regulatory Affairs Specialist  
1450 E. Brooks Road  
Memphis, Tennessee 38116

Re: K121443

Trade/Device Name: Journey II CR Knee System  
Regulation Number: 21 CFR 888.3560  
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained  
cemented prosthesis  
Regulatory Class: II  
Product Code: JWH  
Dated: May 14, 2012  
Received: May 15, 2012

Dear Ms. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

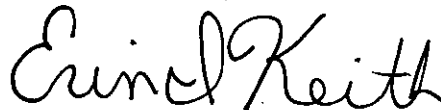
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "E. Keith".

for

Mark N. Melkerson

Director

Division of Surgical, Orthopedic  
and Restorative Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

**Premarket Notification  
Indications for Use Statement**

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510(k) Number (if known): K121443

Device Name: Journey II CR Knee System

**Indications for Use:**


Total knee components are indicated for rheumatoid arthritis; post-traumatic arthritis, osteoarthritis, or degenerative arthritis; failed osteotomies, unicompartmental replacement, or total knee replacement. Posterior stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

The Journey II Total Knee system components are indicated for use only with cement and are single use devices.

|                             |          |        |                           |
|-----------------------------|----------|--------|---------------------------|
| Prescription Use            | <u>X</u> | AND/OR | Over-The-Counter<br>Use   |
| (Part 21 CFR 801 Subpart D) |          |        | (21 CFR 807<br>Subpart C) |

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NEEDED)

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 Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K121443